

AUG 24 1999

FREEDOM OF INFORMATION SUMMARY

SUPPLEMENTAL NEW ANIMAL DRUG APPLICATION

NADA 140-819

Strongid® 48
(pyrantel tartrate)

Sponsored by:

Pfizer, Inc.

NADA 140-819

FOIS 1

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FREEDOM OF INFORMATION SUMMARY

I. GENERAL INFORMATION

NADA Number: 140-819

Sponsor: Pfizer, Inc.
235 East 42nd Street
New York, NY 10017-5755

Established Name: pyrantel tartrate

Tradename: Strongid® 48

Marketing Status: OTC

Supplement Effect: This supplement provides for revised feeding instructions. It also provides for movement of the parasite *Triodontophorus* spp. from the Large Strongyles to the Small Strongyles in the indications section.

II. INDICATIONS FOR USE

Strongid® 48 is recommended for the prevention of *Strongylus vulgaris* larval infestation in horses. For control of the following parasites in horses: Large Strongyles (adults): *S. vulgaris*, *S. edentatus*; Small Strongyles (adults and fourth-stage larvae): *Cyathostomum* spp., *Cylicocyclus* spp., *Cylicostephanus* spp., *Cylicodontophorus* spp., *Poteriostomum* spp., *Triodontophorus* spp.; Pinworms (adults and fourth-stage larvae): *Oxyuris equi*; Ascarids (adults and fourth-stage larvae): *Parascaris equorum*.

III. DOSAGE FORM, ROUTE OF ADMINISTRATION, AND RECOMMENDED DOSAGE

- A. *Dosage Form*: Type A Medicated Article and Type C Medicated Feeds
- B. *Route of Administration*: Oral
- C. *Approved Dose*: Feed continuously at the rate of 1.2 milligrams per pound (2.64 milligrams per kilogram) of body weight daily.

IV. EFFECTIVENESS

Additional effectiveness studies were not necessary for the proposed label changes.

V. ANIMAL SAFETY

Additional safety studies were not necessary for the proposed label changes.

VI. AGENCY CONCLUSIONS

The data submitted in support of this supplemental NADA comply with the requirements of section 512 of the Act and demonstrate that pyrantel tartrate, when used under the proposed conditions of use, is safe and effective for the listed indications.

In accordance with 21 CFR 514.106(b)(1)(vii), this is a category I change. The approval of this change did not require a reevaluation of the safety and effectiveness data in the parent application.

Under section 512(c)(2)(F)(iii) of the FFDCA, this approval for non food producing animals does not qualify for marketing exclusivity because the supplemental application does not contain substantial evidence of the effectiveness of the drug involved, or any studies of animal safety required for the approval and conducted or sponsored by the applicant.

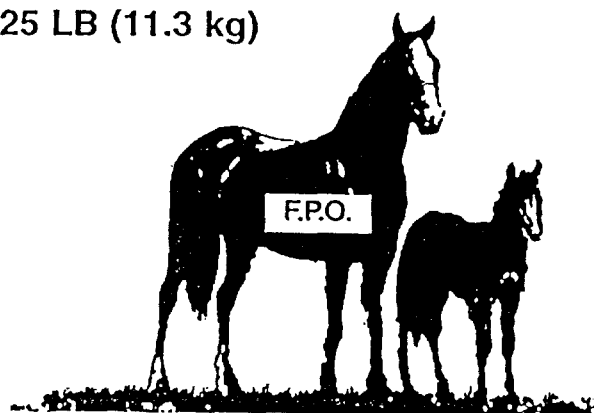
VII. APPROVED PRODUCT LABELING

Facsimile labeling is attached:

Type A Medicated Article
Type C Blue Bird Labeling
4.8 g/lb
9.6 g/lb

NET WT 25 LB (11.3 kg)

1165



Strongid[®] C

(pyrantel tartrate)
Equine Anthelmintic
Medicated
For Continuous Feeding

For the prevention of
Strongylus vulgaris larval infestation in horses

For Control of the Following Parasites in Horses

LARGE STRONGYLES (adults)—*S. vulgaris*, *S. edentatus*

SMALL STRONGYLES (adults and fourth-stage larvae)—

Cyathostomum spp., *Cylicocycclus* spp., *Cylicostephanus* spp.,

Cylicodontophorus spp., *Poteriostomum* spp., *Triodontophorus* spp.

PINWORMS (adults and fourth-stage larvae)—*Oxyuris equi*

ASCARIDS (adults and fourth-stage larvae)—*Parascaris equorum*

Active Drug Ingredient

pyrantel tartrate 1.06% (4.8 g/lb)

Guaranteed Analysis

Crude Protein, not less than	12.5%
Crude Fat, not less than	2.0%
Crude Fiber, not more than	22.0%

Ingredients

Dehydrated Alfalfa Meal, Wheat Middlings, Ground Corn, Cane Molasses, and Preserved with Propionic Acid.

See Back Panel for Complete Use Directions



03-4602-45-1

000001

Strongid C[®]

(pyrantel tartrate)

Equine Anthelmintic

MIXING AND FEEDING DIRECTIONS

Strongid C (pyrantel tartrate) is to be administered on a continuous basis either as a top-dress or mixed in the horse's daily grain ration at the rate of 1.2 mg pyrantel tartrate per pound of body weight daily. To achieve this dose administer 1 oz of Strongid C per 250 lb of body weight. (A Strongid C measuring cup is enclosed.) Strongid C should be administered for the entire period that the animal is at risk to internal parasites. Unprotected animals that have grazed may already have an established *S. vulgaris* larval infestation. Before administering Strongid C, these animals should be treated with a therapeutic dose of a larvicidal product.

Foals may be administered Strongid C as soon as consistent intake of grain mix is occurring. This is generally between two to three months of age.

Strongid C may be used in mares at any stage of pregnancy or lactation. Stallion fertility is not affected by the use of Strongid C.

TOP-DRESS DIRECTIONS	
LB BODY WEIGHT	OUNCES PER DAY OF STRONGID C
250	1
500	2
750	3
1000	4
1250	5

(Measuring Cup Enclosed)

MEDICATED GRAIN MIX DIRECTIONS			
LB OF MEDICATED GRAIN MIX PER 100 LB OF BODY WEIGHT	LB OF STRONGID C	LB OF NON-MEDICATED FEED	CONCENTRATION GRAMS PER TON
2.0	25	1975	120
1.5	33	1967	160
1.0	50	1950	240
0.5	100	1900	480
0.2	250	1750	1200

CAUTION: Consult your veterinarian before using in severely debilitated animals and for assistance in the diagnosis, treatment and control of parasitism. Do not mix in feeds containing bentonite.

WARNING: Not for use in horses intended for food.

03-4603-45-1



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Animal Health
Kenilworth, PA 19034, USA
Div. of Pfizer Inc.
NY, NY 10017



PROOF OF PURCHASE



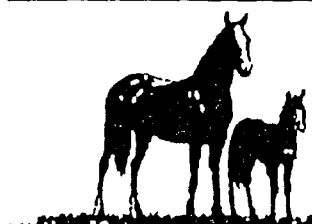
Strongid C
1165

0 87219 01165 2

000002

NET WEIGHT 10 LB (4.5 kg)

1167



Strongid® C 2X™

(pyrantel tartrate)
Equine Anthelmintic
Medicated For Continuous Feeding

For the prevention of *Strongylus vulgaris* larval infestation in horses

For Control of the Following Parasites in Horses

LARGE STRONGYLES (adults)–*S. vulgaris*, *S. edentatus*

SMALL STRONGYLES (adults and fourth-stage larvae)–

Cyathostomum spp., *Cylicocyclus* spp., *Cylicostephanus* spp.,

Cylicodontophorus spp., *Poteriostomum* spp., *Triodontophorus* spp.

PINWORMS (adults and fourth-stage larvae)–*Oxyuris equi*

ASCARIDS (adults and fourth-stage larvae)–*Parascaris equorum*

Active Drug Ingredient

pyrantel tartrate..... 2.11% (9.6 g/lb)

Guaranteed Analysis

Crude Protein, not less than..... 11.5%

Crude Fat, not less than..... 1.5%

Crude Fiber, not more than..... 22.0%

Ingredients

Dehydrated Alfalfa Meal, Wheat Middlings, Cane Molasses, and Preserved
with Propionic Acid.

(SEE OTHER PANELS FOR FURTHER USE DIRECTIONS)



Panel 1 01-5058-45-1

5"(W) X 3.8"(H)



PMS 463



PMS 347



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600003

Strongid® C 2X™

(pyrantel tartrate)

MIXING AND FEEDING DIRECTIONS

Strongid® C 2X™ (pyrantel tartrate) is to be administered on a continuous basis either as a top-dress or mixed in the horse's daily grain ration at the rate of 1.2 mg pyrantel tartrate per pound of body weight daily. To achieve this dose administer 0.5 oz of Strongid C 2X per 250 lb of body weight. (A Strongid C 2X measuring cup is enclosed. Please note it is different in size and shape from the original Strongid C measuring cup due to the higher concentration of Strongid C 2X.) Strongid C 2X should be administered for the entire period that the animal is at risk to internal parasites. Unprotected animals that have grazed may already have an established *S. vulgaris* larval infestation. Before administering Strongid C 2X, these animals should be treated with a therapeutic dose of a larvicidal product.

Foals may be administered Strongid C 2X as soon as consistent intake of grain mix is occurring. This is generally between two to three months of age.

Strongid C 2X may be used in mares at any stage of pregnancy or lactation. Stallion fertility is not affected by the use of Strongid C 2X.

(SEE OTHER PANELS FOR FURTHER USE DIRECTIONS)



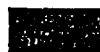
Panel 2 01-5058-45-1
5" (W) X 3.8" (H)



PMS 463



PMS 347



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000004

Strongid® C 2X™

(pyrantel tartrate)

TOP-DRESS DIRECTIONS		MEDICATED GRAIN MIX DIRECTIONS			
LB BODY WEIGHT	OUNCES PER DAY OF STRONGID C 2X	LB OF MEDICATED GRAIN MIX PER 100 LB OF BODY WEIGHT	LB OF STRONGID C 2X	LB OF NON-MEDICATED FEED	CONCENTRATION GRAMS PER TON
250	0.5	2.0	12.5	1987.5	120
500	1.0	1.5	16.5	1983.5	160
750	1.5	1.0	25.0	1975	240
1000	2.0	0.5	50.0	1950	480
1250	2.5	0.2	125.0	1875	1200
(Measuring Cup Enclosed)					

Caution: Consult your veterinarian before using in severely debilitated animals and for assistance in the diagnosis, treatment and control of parasitism. Do not mix in feeds containing bentonite.

⚡ **Warning:** Not for use in horses intended for food. ⚡

(SEE OTHER PANELS FOR FURTHER USE DIRECTIONS)

Strongid® C 2X™ is the Pfizer Inc trademark for pyrantel tartrate.



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Animal Health

Exton, PA 19341, USA
Div of Pfizer Inc, NY, NY 10017

TAKE TIME



OBSERVE LABEL DIRECTIONS

01-5058-45-1

Panel 3 01-5058-45-1
5"(W) X 3.8"(H)



PMS 463



PMS 347



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000005

NET WEIGHT 10 LB (4.5 kg)

1167

Strongid[®] C 2X[™]

(pyrantel tartrate)

Equine Anthelmintic

Medicated For
Continuous Feeding



Panel 4 01-5058-45-1
5"(W) X 3.8"(H)



PMS 463



PMS 347



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000006

Strongid® 48

(pyrantel tartrate)

Type A Medicated Article

Equine Anthelmintic

Active Drug Ingredient:

Pyrantel tartrate.....10.6% (48 g/lb)

Indications for Use:

For the prevention of *Strongylus vulgaris* larval infestation in horses.

For control of the following parasites in horses:

Large Strongyles (adults): *S. vulgaris*, *S. edentatus*

Small Strongyles (adults and fourth-stage larvae): *Cyathostomum* spp., *Cylicocyclus* spp., *Cylicostephanus* spp., *Cylicodontophorus* spp., *Poteriostomum* spp., *Triodontophorus* spp.

Pinworms (adults and fourth-stage larvae): *Oxyuris equi*

Ascarids (adults and fourth-stage larvae): *Parascaris equorum*

CAUTION: For use in manufacturing of equine feeds only.

CAUTION: Certain components of animal feeds, including medicated premixes, possess properties that may be a potential health hazard or a source of personal discomfort to certain individuals who are exposed to them. Human exposure should, therefore, be minimized by observing the general industry standards for occupational health and safety. Precautions such as the following should be considered: dust masks or respirators and protective clothing should be worn; dust-arresting equipment and adequate ventilation should be utilized; personal hygiene should be observed; wash before eating or leaving a work site; be alert for signs of allergic reactions—seek prompt medical treatment if such reactions are suspected.

STORE IN A DRY, COOL PLACE

SEE BACK PANEL FOR FURTHER USE DIRECTIONS

Net Weight: 50 lb (22.6 kg)

NADA #140-819, Approved by FDA

998 90-7268-00-X1



Y9071-05H

Strongid® 48
(pyrantel tartrate)



- reactions are suspected.

STORE IN A DRY, COOL PLACE
SEE BACK PANEL FOR FURTHER USE DIRECTIONS

Net Weight: 50 lb (22.6 kg)

NADA #140-819, Approved by FDA

998 90-7268-00-X1

Stron
(pyrantel tartra



Mitered Corner, Pinch Bottom Style, Flush Cut
Open End
(Stone Printing)

16" X 6" X 32"
@ 40%



Black 30% Black

**NOTE: Background color denotes Brown Kraft
bag for approval purposes only. Does not print.**

90-7268-00-X1 Draft #1 8/6/99



01100872194907133001

TAKE TIME

OBSERVE LABEL
DIRECTIONS

Strongid® 48

(pyrantel tartrate)

Type A Medicated Article

Equine Anthelmintic

Mixing and Use Directions

Strongid is to be administered on a continuous basis either as a top-dress or mixed in the horse's daily grain ration at the rate of 1.2 mg/lb (2.64 mg/kg) of body weight daily. The duration of administration is for the period during which the horse is at risk of exposure to internal parasites.

Foals may be treated at such time when consistent intake of grain mix is occurring. This is generally between 2 and 3 months of age.

Strongid may be used in mares at any stage of pregnancy or lactation. Stallion fertility is not affected by the use of Strongid.

Typical Mixing Directions to Deliver 1.2 mg/lb (2.64 mg/kg)

Ib of Medicated Grain Mix per 100 Ib of Body Weight	Ib of Strongid 48	Ib of Nonmedicated Feed	Resulting Concentration (g/ton)
2.00	2.5	1997.5	120
1.50	3.3	1996.7	160
1.00	5.0	1995.0	240
0.50	10.0	1990.0	480
0.20	25.0	1975.0	1200

Ib of Medicated Top-Dress per 100 Ib of Body Weight	Ib of Strongid 48	Ib of Nonmedicated Feed	Resulting Concentration (g/ton)
0.04	125.0	1875.0	6000
0.025	200.0	1800.0	9600
0.02	250.0	1750.0	12000
0.0125	400.0	1600.0	19200

⬤ **WARNING:** Not for use in horses intended for food. ⬤

CAUTION: Consult your veterinarian before using in severely debilitated animals and for assistance in the diagnosis, treatment, and control of parasitism. Do not mix in feeds containing bentonite.

998 90-7268-00-X1

• Made in USA



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Animal Health

Exton, PA 19341, USA

Div. of Pfizer Inc.

NY, NY 10017

Strongid® 48
(pyrantel tartrate)

Y9071-05H

